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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/089,846 | 06/06/2002 | John Carter | 3920-0110P | 5250 |

2292 7590 01/19/2007
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| EXAMINER |
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CHOI, FRANK I

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| ART UNIT | PAPER NUMBER |
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1616

| SHORTENED STATUTORY PERIOD OF RESPONSE | NOTIFICATION DATE | DELIVERY MODE |
|--|-------------------|---------------|
| 3 MONTHS | 01/19/2007 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/19/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/089,846 | CARTER, JOHN | |
| | Examiner | Art Unit | |
| | Frank I. Choi | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89-102, 104-108 and 121-158 is/are pending in the application.
- 4a) Of the above claim(s) 102, 144 and 156 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89-96, 98, 99, 101, 104-108, 121-134, 146-148, 151-155 and 157 is/are rejected.
- 7) ☒ Claim(s) 97, 100, 135-143, 145, 149, 150 and 158 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/22/2006 has been entered.

Claim Objections

Claims 97,100,149,150,158 are objected to as being dependent upon a rejected base claim, but would be allowable to the extent the claim reads on the elected invention if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Examiner did not state that the claims would be allowable if one merely recited sublimed sulfur; the claims must be directed to the elected invention: the elected species are copper orotate, manganese orotate, iron orotate, zinc orotate, sodium salicylate, assimilable sulfur and proline.

Claims 135-143,145 are allowable to the extent the claims read on the elected invention, however, the claims are objected to as they are broader in scope than the elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 89-96,98,99,101,104-108,121-134, 146-148,151-155, 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US Pat. 5,654,011) in view of Riley et al. (US Pat. 5,948,443, Wawretschek et al. (US Pat. 4,061,741), Herschler (US Pat. 4,514,421), Herschler (US Pat. 4,616,039) and Bounous et al. (US Pat. 5,290,571).

Jackson et al. disclose compositions and methods for providing dietary supplements to meet the needs of pre-perimenopausal women, including pregnant women, and to reduce the risk of cancer comprising copper, manganese, zinc, iron and vitamin C (Column 2, lines 25-51, Column 4, lines 13-23, Column 8, lines 30-68).

Riley et al. discloses a composition and method of reducing the risk of cancer by providing dietary supplements to women which comprise aspirin or bioequivalent forms, such as salicylic acid or other salicylates, iron, zinc, manganese, copper and Vitamin C (Column 9, lines 30-55, Column 21, lines 7-63, Table III).

Wawretschek et al. disclose that the analgesic efficiency of sodium salicylate can be reinforced by combining with a salt of orotic acid (Claims 10, 30,39).

Hershler (US Pat. 4,514,421) disclose that administration of methylsulfonylmethane (MSM) and ascorbic acid and that administration of MSM resulted in reduction of tumor mass (Column 12, lines 7-47).

Hershler (US Pat. 4,616,039) disclose that methylsulfonylmethane is an assimilable source of sulfur (Abstract).

Bounous et al. disclose a composition containing proline to which is added vitamin C, iron, zinc, copper which is used to treat cancer (Column 6, lines 10-31, Table 1, Column 7, Column 24, lines 25-68, Table 10).

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The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of copper orotate, manganese orotate, iron orotate, sodium salicylate, a source of assimilable sulfur, proline and vitamin C. However, the prior art amply suggests the same as the prior art discloses dietary supplements which combine various nutrients, such as copper, manganese, vitamin C with salicylates for use in women and reducing the risk of cancer, the combination of sodium salicylate and salts of orotate to increase the efficacy of the sodium salicylate, the use of copper, manganese, iron and vitamin C for use in pregnant women and reducing the risk of cancer, MSM for treatment of cancer and proline which can be combined with other nutrients, such as copper, iron, zinc and vitamin C and is used to treat cancer. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art by providing the copper, iron, zinc and manganese as salts of orotate so as to increase the efficacy of the sodium salicylate and to combine copper, iron, zinc and manganese with sodium salicylate and vitamin C with the expectation that the composition would be suitable for use in pregnant women and for treatment of cancer, to further add proline with the expectation that the same would be suitable for treatment cancer and to add MSM as it is effective in treating cancer.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Action.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a

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secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

The Applicant argues that Wawretsheck is not concerned with treatment of cancer, and, thus is irrelevant. The Applicant provides no evidence that increasing the analgesic effect of a compound is irrelevant in the treatment of cancer. Similarly, with respect to Jackson and Riley, the Applicant provides not evidence that providing multivitamins and nutrients would not provide a nutritional benefit to cancer patients. The claims are directed to treating a neoplastic disease, however, the claims do not exclude treatment in terms of providing nutritional benefit to the cancer patient. It cannot be concluded from the working example that each of the components contributed to the observed effect. In fact, is it equally possible that one or more of the components provide no benefit other than a nutritional benefit. Also, the working example does not support the entire scope of the claims as the working example treated a specific tumor with a combination of the specified components in the specified amounts.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner

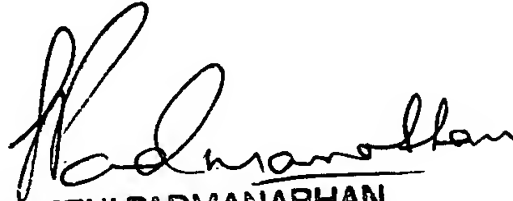
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maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
January 8, 2007


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER